



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 8, 2018

Mr. David Chi
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

Subject: Application to amend the expiration date, acreage limitation and product label of MON 89034 x MIR162 x MON 87411
EPA Registration Number: 524-635
Submission Date: September 28, 2017
OPP Decision Number: 536154

Dear Mr. Chi:

On September 28, 2017, you submitted an application to amend the subject product registration and label. Your application requested to remove the expiration date and modify the acreage limitation. This amendment request, submitted in connection with registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you comply with the updated terms and conditions as described in this letter.

1. Submit and/or cite all data required for registration or registration review of your product when the EPA requires all registrants of similar products to submit such data.
2. The subject registration is limited to *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production (vector PV-ZMIR245) in event DAS-59122-7 (OECD Unique Identifier: MON-89034-3), *Bacillus thuringiensis* Vip3Aa20 protein and the genetic material necessary for its production (vector pNOV1300) in event MIR162 (OECD Unique Identifier: SYN-IR162-4), and *DvSnf7* dsRNA [Double-stranded ribonucleic acid transcript comprising a *DvSnf7* inverted repeat sequence derived from western corn rootworm (*Diabrotica virgifera virgifera*)] and *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for their production (vector PV-ZMIR10871) in event MON 87411 (OECD Unique Identifier: MON-87411-9) for use in field corn.
3. This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
4. Planting seed containing this plant-incorporated protectant may only be planted for the purposes of agronomic evaluation, seed increase, and production in breeding nurseries as specified in the terms of this registration and on the labeling. Commercial plantings of this product for the purposes of grain production and controlling insect pests are prohibited.

5. Plants that contain this plant-incorporated protectant may be grown on up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per registrant per year. Harvested seed should not be allowed for sale as commercial seed in the U.S. under the current terms of this registration but any non-treated seed grain containing MON 89034 x MIR162 x MON 87411 may be sold as grain.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6. A stamped copy of the labeling is enclosed for your records.

Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

- Basic CSF dated 05/10/2016

If you have any questions, please contact Matt Weiner by phone at (703) 347-0333 or via email at weiner.matthew@epa.gov.

Sincerely,



Alan Reynolds, Team Leader
Emerging Technologies Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

ACCEPTED

02/08/2018

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 524-635

Plant-Incorporated Protectant Label
MON 89034 × MIR162 × MON 87411

Insect-Protected, Herbicide-Tolerant Corn
(OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × MIR162 × MON 87411 (OECD Unique Identifier MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9).....≤ 0.0027%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × MIR162 × MON 87411 (OECD Unique Identifier MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9).....≤ 0.0071%*

Bacillus thuringiensis Vip3Aa20 protein and the genetic material (vector pNOV1300) necessary for its production in MON 89034 × MIR162 × MON 87411 (OECD Unique Identifier MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9).....≤ 0.014%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × MIR162 × MON 87411 (OECD Unique Identifier MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9)≤ 0.0086%*

dsRNA transcript comprising a DvSnf7 inverted repeat sequence derived from *Diabrotica virgifera virgifera*, and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × MIR162 × MON 87411 (OECD Unique Identifier MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9)≤ 0.00000037%*

Other Ingredients:

Phosphomannose isomerase (PMI), marker protein and the genetic material (Vector pNOV1300) necessary for its production in MON 89034 × MIR162 × MON 87411 (OECD Unique Identifier MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9).....≤ 0.00085%*

The marker protein CP4 EPSPS and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × MIR162 × MON 87411 (OECD Unique Identifier MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9)≤ 0.029%*

*Percentage (wt/wt) on a dry weight basis for whole plant (forage)

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA Registration No. 524-635

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

This product may be used for breeding purposes, agronomic testing, increasing inbred seed stocks, and producing hybrid seed on up to a total of 20,000 acres per county and up to a combined United States (US) total of 250,000 acres per plant incorporated protectant (PIP) active ingredient per registrant per year. Commercial plantings of this product, for the purposes of grain production and controlling corn insect pests, are prohibited.

Harvested seed are not allowed for sale as a commercial seed in the US under the current conditions of this registration but any non-treated seed containing MON 89034 × MIR162 × MON 87411 may be sold as grain.

There are no refuge requirements for planting MON 89034 × MIR162 × MON 87411 Corn.